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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR CONFIRMATION NO. APPLICATION NO. FILING DATE 10/532,847 04/27/2005 Josef Ehrenfreund 70142 EXAMINER 26748 07/12/2006 7590 SYNGENTA CROP PROTECTION, INC. QAZI, SABIHA NAIM PATENT AND TRADEMARK DEPARTMENT ART UNIT PAPER NUMBER 410 SWING ROAD GREENSBORO, NC 27409 1616

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | _ |
|---|--|---|---|
| | 10/532,847 | EHRENFREUND ET AL. | |
| Office Action Summary | Examiner | Art Unit | _ |
| | Sabiha Qazi | 1616 | |
| The MAILING DATE of this communication a Period for Reply | ppears on the cover sheet v | ith the correspondence address | |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perions are to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUN 1.136(a). In no event, however, may a nd will apply and will expire SIX (6) MO ute, cause the application to become A | ICATION. reply be timely filed NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). | |
| Status | | | |
| 1) Responsive to communication(s) filed on 27 | April 2005. | | |
| • | nis action is non-final. | • | |
| 3) Since this application is in condition for allow | ance except for formal ma | ters, prosecution as to the merits is | |
| closed in accordance with the practice under | Ex parte Quayle, 1935 C. | D. 11, 453 O.G. 213. | |
| Disposition of Claims | | | |
| 4) Claim(s) 1-10 is/are pending in the application | on. | | |
| 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration. | | | • |
| 5) Claim(s) is/are allowed. | | | |
| 6)⊠ Claim(s) <u>1-5,9 and 10</u> is/are rejected. | | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) <u>6-8</u> are subject to restriction and/or | election requirement. | | |
| Application Papers | | | |
| 9)☐ The specification is objected to by the Exami | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | |
| Replacement drawing sheet(s) including the corre | • | | |
| 11) The oath or declaration is objected to by the | Examiner. Note the attache | d Office Action or form P10-152. | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of: 1. Certified copies of the priority docume | | § 119(a)-(d) or (f). | |
| 2. Certified copies of the priority documents have been received in Application No | | | |
| 3. Copies of the certified copies of the pri | iority documents have bee | received in this National Stage | |
| application from the International Bure | au (PCT Rule 17.2(a)). | | |
| * See the attached detailed Office action for a lis | st of the certified copies no | received. | |
| Attachment(s) | _ | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | | Summary (PTO-413) (s)/Mail Date | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date | | Informal Patent Application (PTO-152) | |

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Non-Final Office Action

Claims 1-10 are pending. Claims 1-5, 9, and 10 are examined.

Others are withdrawn from consideration as non-elected invention. No claim is allowed at this time.

Summary of this Office Action dated Friday, July 7, 2006

- 1. Election/Restrictions
- 2. Information Disclosure Statement
- 3. Copending Applications
- 4. Specification
- 5. 35 USC § 112 --- First Paragraph Scope of Enablement Rejection
- 6. 35 USC § 102(b) Rejection
- 7. 35 USC § 103(a) Rejection
- 8. Examiner's Notes
- 9. Communication

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 9, and 10, drawn to the compounds of formula (I), classified in class 544, 540, 546, 548, 549, subclass (various).

Group II, claim(s) 6, drawn to compounds of formula (II), classified in class 544, 540, 546, 548, 549, subclass (various).

Group III, claim(s) 7 and 8, drawn to the process of preparing compounds of formula (V), classified in class 544, 540, 546, 548, 549, subclass (various).

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they are drawn to structurally different compounds and their preparations.

During a telephone conversation with Attorney Rebecca Gegick on June 23, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5, 9, and 10. Applicant in replying to this Office action must make affirmation of this election. Claims 6-8 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37

CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the

Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted

in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have

not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the

examination of a particular application, information within their knowledge as to other copending United States

applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco

Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible

minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in

the specification.

35 USC § 112 --- First Paragraph Scope of Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain compounds, does not reasonably provide enablement for all the compounds as presently claimed (for example, Het represents a 5- or 6-membered heterocyclic ring containing one to three heteroatoms, which includes thousands of compounds).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

Presently claimed invention is drawn to a compound of formula (I).

(2) The predictability or unpredictability of the art

There is a lack of predictability in the art. Claims are drawn to large number of compounds which belong to chemically different structure. For example Het in claim 1 formula (1) can be 5-6 membered heterocyclic ring containing one to three heteroatoms, each independently selected from oxygen, nitrogen and sulfur. For example the hetero group includes pyrroyl, pyrazol, thiazolyl, pyridinyl, pyrimidinyl, thienyl, furyl, isothiazolyl, or isoxazolyl. It is impossible to predict the same property for the compounds belonging to all these groups.

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On

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the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), stated:

[I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof.

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. See MPEP 2164.03.

(3) The breadth of the claims

The claims are broad. For example, Het represents a 5- or 6-membered heterocyclic ring containing one to three heteroatoms, which includes thousands of compounds. Furthermore, in claim 2, Het can be pyrroyl, pyrazol,

thiazolyl, pyridinyl, pyrimidinyl, thienyl, furyl, isothiazolyl, or isoxazolyl. This includes an even wider range of compounds. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

(4) The amount of direction or guidance presented

There is no direction or guidance presented for one skilled in the art to make and/or use the wide range of compounds as presently claimed. The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("Nascent technology, however, must be enabled with a 'specific and useful teaching.' The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology."

(5) The presence or absence of working examples

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There are no working examples presented for one skilled in the art to make and/or use the wide range of compounds as presently claimed. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPO 724.

(6) The quantity of experimentation necessary

Since there is no guidance and/or direction provided by the Applicants for the wide variety of the compounds and their preparation and method of use, one skilled in the art would have to go through undue experimentation to make and/or use the instant invention.

The first paragraph of 35 USC 112 requires "...such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains..." The instant invention fails to meet this requirement, as it lacks such full, clear, and concise manner as to enable any person skilled in the art to which it pertains to make and/or use the invention.

35 USC § 102(b) Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by YOSHIKAWA et al.

The reference discloses the compound 1.41 on page 30, which anticipates the instant invention.

See the cited areas in the footnote.

35 USC § 103(a) Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over YOSHIKAWA et al². See the cited areas in the footnote.

Instant claims are considered obvious when Q represents cycloalkyl group having 3 to 10 carbon atoms (last line on page 2) and when Ar represents A1 to A8. See lines 10-25 on page 3.

¹ YOSHIKAWA et al. EP 0 737 682 A1. See the entire document especially lines 36-58 on page 2, lines 1-29 on page 3, compound (I) on page 5, Methods A to E on pages 6 and 7, compound 1.41 on page 30, claims, Table 5 on page 27, and examples

page 27, and examples

2 YOSHIKAWA et al. EP 0 737 682 A1. See the entire document especially lines 36-58 on page 2, lines 1-29 on page 3, compound (I) on page 5, Methods A to E on pages 6 and 7, compound 1.41 on page 30, claims, Table 5 on page 27, and examples

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Instant claims differ from the reference in that they are of different generic scope. It had been held by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. <u>In re</u>
<u>Lemin</u>, 141 USPQ 814 (1964); <u>National Distillers and Chem. Corp. V. Brenner</u>, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds. The instant claimed compounds would have been suggested to one skilled in the art.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have obvious to one skilled in the art.

Examiner's Notes

The proviso in claim 1 is noted by the Examiner.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR

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or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Friday July 7 2006

SABIHA QAZI, PH.D PRIMARY EXAMINER